UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,980	07/17/2000	RICHARD KOLESNICK	D6049	6671

7590 11/14/2003

BENJAMIN ADLER
MCGREGOR & ADLER
8011 CANDLE LANE
HOUSTON, TX 77071

EXAMINER	
HAMUD, FOZIA M	
ART UNIT	**PAPER NUMBER**
1647	18

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Fk copy

Advisory Action	Application No.	Applicant(s)	
	09/554,980	KOLESNICK ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

--Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --

THE REPLY FILED 21 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-4, 6-7, 10*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

ADVISORY ACTION

1. Receipt of Applicant's arguments and amendment, filed on 21 August 2003 in Paper No.17, is acknowledged. Claims 1, 4 and 10 have been amended. Claims 5, 8-9 have been cancelled. Thus claims 1-4, 6-7 and 10 are pending and under consideration.

Claim Rejections - 35 U.S.C. § 102:

2a. The rejection of claims 1, 2, 4, 6, 10 , made under 35 U.S.C. 102(e) as being anticipated by Jain et al. (U. S. Patent 6,010,712), is maintained for reasons of record, as set forth in the office actions mailed on 24 June 2003, in Paper No:16, and on 13 December 2003, in Paper No:13.

Applicants argue that Jain et al. do not provide an enabling disclosure for a method of using b-FGF to treat sepsis. Applicants submit that Jain et al only present an *in vitro* data that shows the effects of b-FGF on white cell adhesion to vascular endothelium, but make no connection between white cells adhesion to vascular endothelium and sepsis. Applicants argue that Jain et al do not show inhibition of cytotoxic white cells adhesion to vascular endothelium would provide a treatment for sepsis. Applicants further argue that endtoxic shock and sepsis are complex biological events that involve multiple cell types and process, and that cell adhesion to endothelium is only one these processes. Applicants submit that Jain et la have not taught that cytotoxic white cells adhesion to vascular endothelium is such a critical step in sepsis. Applicants further argue that Jain et al do not show that b-FGF would be beneficial *in vivo*, and one of ordinary skill art could not practice the method of Jain et al.

Applicants conclude that the method of treating sepsis with b-FGF disclosed by Jain et al is not commensurate with the scope of enablement provided in that disclosure.

Applicants arguments have been considered but are not deemed persuasive. Firstly, Jain et al expressly disclose a method of treating sepsis by administering b-FGF to an animal suffering from said condition, (column 8, lines 34-35 and claims). Secondly, whether Jain et al established a connection between cytotoxic white cell adhesion to vascular endothelium and sepsis is irrelevant, because the Jain et al reference teaches a method of treating the same population by administering the same compound as claimed in the present application, (i.e, sepsis and b-FGF, respectively). Finally, as to Applicants' argument that Jain et al do not provide an enabling disclosure for a method of treating sepsis by administering b-FGF, the Examiner maintains that the test for adequacy of a prior art disclosure to anticipate under 35 U.S.C. § 102, is not the same test as that for adequacy of a patent application disclosure to support claims under 35 U.S.C. §112, as taught by In re Hafner, 161 USPQ 783, (CCPA 1969).

3a. Claims 1, 3, 4 and 7 stand rejected under U.S.C. § 103 as being unpatentable over Jain et al is maintained for reasons of record set forth in the office actions mailed on 24 June 2003 and the one the one mailed 13 December 2002.

Applicants present the same arguments as discussed above in paragraph 2a. Applicants maintain that the Jain et al reference is a mere proposal that invites further experimentation and that there is no reasonable expectation of success of treating sepsis with b-FGF. Applicants further argue that the data of in vitro cell adhesion inhibition disclosed by Jain et al does not show that b-FGF would be beneficial in vivo.

These arguments have been considered but are deemed unpersuasive. Independent claims 1 and 4 have been rejected under 35 U.S.C. 102(e) as being anticipated by Jain et al. (U. S. Patent 6,010,712). Dependent claims 3 and 7 have been reject under U.S.C. § 103 as being unpatentable over Jain et al, because Jain et al reference does not teach the specific regimen recited in claims 3 and 7. However, it would have been obvious to one of ordinary skill in the art at the time of the invention, to administer b-FGF to treat sepsis, as taught by Jain et al, and to optimize both the dosage and duration of said administration, because the optimal dosage for a given patient depends upon weight, age and gender and can be determined by one of ordinary et al in the art.

Conclusion:

4. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
10 November 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600